

REMARKS

The Examiner has objected to the specification on the grounds that it is unclear what Applicant regards as the means 24 for flexing the handle member, means 26 for limiting the flex of the handle member, and means 25 for maintaining the registered placement of the apparatus, and has asked for clarification in the form of examples and definitions.

The means 24 for flexing the handle member is described in detail on Page 8, Lines 10-19 of the specification. In that portion of the specification, it is explained that the “[g]ripping portion 50 of the first handle region 20 and gripping portion 56 of the second handle region 22 are spaced apart a predetermined distance from each other, to essentially provide a means for flexing” (Spec., Page 8, Lines 10-12). By spacing the gripping portions of the handle regions apart from one another, a user is able to manually grip, and then flex one of the housing and the registration maintaining means 25 by pushing the two gripping portions (50, 56) together.

Similarly, the means 26 for limiting the flex of the handle member may also be exemplified by the spacing between the gripping portions (50, 56). As is explained on Pages 8 and 9 of the specification, the placement of a predetermined gap between the gripping members limits the total flex of the housing/registration placement means. First, a “user pinches the gripping members . . . [so that] the distance separating the two gripping portions becomes smaller until end 62 of first gripping portion is in abutment with end 64 of second gripping portion 56.” (Spec. Page 9, Lines 2-4). Thereafter, “the respective gripping portions can be pinched no further and additional flexing . . . is not possible.” (Spec., Page 9, Lines 4-6).

Means for registering placement 25 is additionally described on Page 9 of the specification. Registering placement means 25 includes “lateral straddling member 70, medial

straddling member 72 and biasing means 73.” (Page 9, Lines 9-10). These structural elements cooperate with internal segments of the eye (lateral angle, medial angle, lacrus lacrimalis and caruncula lacrimalis) to register the placement of the housing on the eye.

Applicant believes that the above explanations should adequately explain the terms objected to by the Examiner, and respectfully requests withdrawal of the Examiner’s objections.

In addition to the above, the Examiner has rejected Claims 7-9, 16-18, 26-27 and 29 under 35 U.S.C. §112, second paragraph, based on the contention that they are indefinite as written. Specifically, the Examiner has noted several informalities with the claims, and has required clarification regarding certain terms used in the claims. Applicant notes that Claims 1, 10 and 21 have all been amended, and Claims 7, 8, 16, 17, 27 and 28 have all been deleted. Therefore, Applicant will address the Examiner’s rejection of Claims 9, 18, 26 and 29 only.

The Examiner has rejected Claims 9, 18 and 29 based on the contention that it is not clear what the “means for biasing” as used in those claims. In the specification, the biasing term is explained in detail. For example, on Page 10 of the specification, it is explained that, after the device is flexed, and then positioned on the eye, “the soft tissue is generally biased against the straddling members such that the two are retained in substantial abutment.” (Spec., Page 10, Lines 9-10). Similarly, in describing the operation of the device, the straddling members of the device are first flexed together, and then placed adjacent particular regions of the eye (region encompassed by the lateral angle of the eye, the region encompassed by the medial angle of the eye, the lacus lacrimales and the caruncula lacrimales), and then allowed to deflect back to their original positions. In doing so, and “once fully released, due to the relative spacing between the straddling members, the straddling members are generally biased against the respective soft tissue surrounding the eye due to the biasing means.” (Spec, Page 11, Line 16 – Page 12, Line

5). Thus, the biasing means referred to in Claims 9, 18, and 29 can comprise one or more of the flexibility of the straddling members, and the placement of those members relative to each other on the device, which can individually or together enable the bias of the members against the eye. Therefore, Applicant submits that claims 9, 18 and 29 are not indefinite, as the term “biasing means” is clearly explained in the specification.

The Examiner has additionally rejected Claim 26 based on the contention that the term “the biasing” lacks an antecedent basis. Applicant has amended Claim 26 to clarify that the term “the biasing” is not an element in Claim 26, but instead is a functional term describing the result of the flexibility of the medial and lateral straddling members. As described above, the straddling members may be flexible to enable the device to be flexed, inserted into the eye, and then released, thereby “biasing” the device against the soft tissue of the eye. Thus, as amended Claim 26 correctly states that the flexibility of the members “facilitate[s] biasing of the straddling members.”

Applicant submits that, based on the above, the Examiner’s rejections of the claims under §112 has been overcome, and respectfully requests withdrawal of those rejections.

Substantively, the Examiner has rejected Claims 1-29 under 35 U.S.C. §102(b), as being anticipated by U.S. Patent No. 5,169,384, issued to Bosniak et al (Bosniak ‘384). Applicant respectfully traverses the Examiner’s rejections. To expedite the prosecution of the application, however, Applicant has amended the claims to better clarify the invention. Specifically, Claims 1, 10 and 21 have been amended to clarify that the registering placement means enables at least one of the lateral straddling member and the medial straddling member to be registerably placed within one or more of a region encompassed by a lateral angle of an eye, a region encompassed by a medial angle of that same eye, a lacus lacrimalis of the eye and the caruncula lacrimalis of

the eye. As will be explained further below, none of the references cited by the Examiner, including Bosniak '384, teach, disclose or even suggest such an embodiment, either alone or in combination with one another.

Specifically, Bosniak '384 teaches a device for the external application of iontophoresis in the general eye area. As can be seen in Fig. 1 of that reference (the closest embodiment), and as explained in the specification, the device overlies the eyelids (34A and 34B), enabling a concentric array of electrodes (38A, 38B, 40A and 40B) to provide for transcutaneous electrical neurostimulation (TENS). (Bosniak '384, Col. 3, Lines 57-62).

On the other hand, the present invention specifically recites the registered placement means cooperates with internal eye tissues, i.e. under the eyelid itself. The present invention enables the cooperation with the region encompassed by the lateral angle of the eye (the lateral region of the eye between the top and bottom eyelids), the region encompassed by the medial angle of the eye (medial region between the top and bottom eyelids), the lacus lacrimalis (triangular space in medial angle), and the caruncula lacrimalis (conical soft tissue that fills up the lacus lacrimalis). All of these ocular features are internal ocular structures, which are not addressed at all by Bosniak '384

From the above differentiation, it is clear that Bosniak '384 does not include means for registering the placement of any structure at all within one or more of a region encompassed by a lateral angle of an eye, a region encompassed by a medial angle of an eye, the lacus lacrimalis, and the caruncula lacrimalis, as claimed in the present Claims 1, 10, and 21. In fact, Bosniak '384 entirely teaches away from such a registering placement means, as Bosniak '384 is specifically directed to a device which overlays the eyelids, and thus is not directed to registering the placement of the device within the internal structures of the eye at all. Therefore, Applicant

submits that Claims 1, 10 and 21 are not taught, disclosed or suggested by Bosniak '384.

Based on the above, Applicant submits that all of Claims 1, 10 and 21 should now be in condition for allowance. Further, the remaining claims in the application, namely Claims 2-6, 9, 11-15, 18, 20, 22-26, and 29, all depend from one of Claims 1, 10 and 21, and should also now be in condition for allowance. Therefore, reconsideration and passage to allowance of Claims 1-6, 9-15, 18, 20-26, and 29 is respectfully requested.

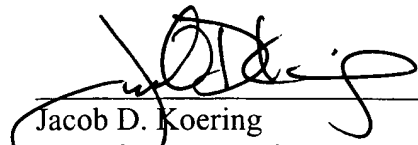
Applicant notes that the Examiner considers the claims replete with vague and indefinite language. Applicant believes that the above explanations, in combination with the amendments and deletions made, clarifies any remaining clarity issues with the claims. If the Examiner has further questions, however, a telephone call to the undersigned is respectfully requested.

Should anything further be required, a telephone call to the undersigned, at (312) 226-1818, is respectfully invited.

Respectfully submitted,

FACTOR & PARTNERS, LLC

Dated: May 5, 2003



Jacob D. Koering
One of Attorneys for Applicant

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 5, 2003.

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